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Registered number 1116828

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Dr Margaret Helliwell
Vice chair
National Institute for Health and Care Excellence
10 Spring Gardens
London SW1A 2BU

Dear Margaret

Re: Final Appraisal Determination: Enzalutamide for metastatic hormone relapsed prostate cancer previously treated with a docetaxel-containing regimen

Grounds of Appeal: Ground 1a): In making the assessment that preceded the recommendation, NICE has failed to act fairly

1.1: The Final Appraisal Determination (FAD) guidance states in section 1.2 that ‘The use of enzalutamide for treating metastatic hormone-relapsed prostate cancer previously treated with abiraterone is not covered by this guidance.’

When one of our members queried the interpretation of this statement from the NICE Committee in specific reference to the question that whether the use of enzalutamide was being recommended in a patient with metastatic hormone-relapsed prostate cancer if they had previously received abiraterone, the reply was that *‘The Committee felt that they had not seen sufficient evidence to allow them to make a recommendation regarding the use of enzalutamide in patients previously treated with abiraterone. Since there is no recommendation for this situation, commissioners would need to make their own decisions regarding funding. (Commissioners are required to make funding available where NICE recommends a treatment.)’* Clearly, this is not ensuring fairness and uniform application of available treatment modalities across the country. This is likely to result in variation in local commissioning thereby jeopardising the very principle of ensuring uniformity of access based on NICE approval.

We appeal that NICE should remove section 1.2 of the FAD. The final guidance should **only** have section 1.1 (Enzalutamide is recommended within its marketing authorisation as an option for treating metastatic hormone-relapsed prostate cancer in adults whose disease has progressed during or after docetaxel containing chemotherapy, only if the manufacturer provides enzalutamide with the discount agreed in the patient access scheme).

This proposal would prevent any confusion in the interpretation of the guidance at local commissioning levels and ensure that patients across the country have an equal access to the drug (enzalutamide).

The appellant wishes to be heard by a written appeal.

Yours sincerely

British Uro-oncology Group (BUG) Executive Committee

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